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ABSTRACT

Does Europe have an innovation policy? The case of EU economic law*

This paper is the first of a larger project aimed at exploring, among other things, whether Europe has a consistent innovation policy in the context of EU economic law (competition policy, intellectual property law, sector regulation). As such, its primary aim is to present our approach for answering this question and outline the anticipated contributions of the project. Part I of the paper sets forth the theoretical foundations of the project--namely an integrated approach to economic law that moves beyond apparent conflicts and assumes innovation as the starting point. Taking this as the foundation, the two primary components of the project are described. First, a theoretical component involving the development of an analytical grid to be used to identify ways in which economic law impacts innovation, and second an applied component that explores observable instances where choices, both implicit and explicit, are made regarding innovation in economic law. Part II of the paper builds on this and offers a preliminary illustration of the proposed analysis in the context of pharmaceuticals, specifically drug reformulation regulatory gaming.

JEL Classification: K21, L41, O31, O34 and O38
Keywords: antitrust, economic law, innovation and pharmaceuticals

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INTRODUCTION

It is remarkable that, in major policy initiatives where innovation plays a central role, such as the Lisbon Agenda and its successor Europe 2020, little attention is paid to those areas of the law which influence the incentives to innovate, namely competition law, intellectual property law, sector-specific regulation (especially electronic communications regulation) and standardization (hereinafter 'EU economic law').[1]

For instance, in the recent Communication 'Innovation Union'[2], it is stated that '[t]he EU Patent has become a symbol for Europe's failure on innovation.'[3] Similarly, one reads that 'standards play an important role for innovation'[4] so that standard-setting must be improved 'to enable interoperability and foster innovation in fast-moving global markets.'[5] As far as competition policy is concerned, the Commission acknowledges that its relationship with intellectual property 'requires in-depth consideration'[6] while giving competition policy a role in 'safeguarding against the use of intellectual property rights for anti-competitive purposes.'[7] These statements all seem obvious, but they reflect trade-offs which have not been explicited, much less discussed. Furthermore, they are not all consistent with one another. What is more, as the saying goes, the proof of the pudding is in the eating: we do not know if and how the actual practice at EU level, as reflected in enactments, decisions, notices, etc. measures up to these statements.

This paper outlines the contribution to be made by our research group to the question whether Europe has an innovation policy, as far as EU economic law is concerned. The first part (1) sets out our research approach, while the second part (2) offers a first example of how it can be applied, in the analysis of recent decisions in the pharmaceutical sector.

1. RESEARCH APPROACH

This project puts innovation at the center and takes an integrated approach to economic law, which goes beyond apparent conflicts. It conducts an in-depth analysis of EU economic law from that approach, upon which further research and policy development can build.

Here 'innovation' is understood as the introduction of new products, services, business, marketing or manufacturing processes, etc. which increase consumer welfare. It is assumed that innovation is desirable, in line with statements such as the Lisbon Agenda. Furthermore, it is assumed that in economic law, fostering innovation is a valid objective.

[1] E.g. L. Soete, *From Industrial to Innovation Policy*, J. IND. COMPET. TRADE 273–284 (2007); L. Soete, B. Verspagen and B. ter Weel, "Systems of Innovation", CPB Discussion Paper 138 (2010).
[2] Communication from the Commission 'Europe 2020 Flagship Initiative: Innovation Union' COM(2010) 546 final 6.10.2010.
[3] *Id*. at 15.
[4] *Id*. at 16.
[5] *Id*. at 17.
[6] *Id*. at 19.
[7] *Id*. at 20.

This project builds on recent work by Larouche, especially a contribution to the WRR Infrastructure project[8] and an article on the *Microsoft* case;[9] the latter found that *Microsoft* is best understood as a choice for incremental over breakthrough innovation, although such choice is never justified or even explicited.

1.1. **Research questions**

The project is divided into two main stages, with a conclusion.

Stage 1 (theoretical): In the abstract, how does economic law impact innovation? If economic law could be designed from scratch, which issues arise, which choices (trade-offs) must be made with respect to innovation?

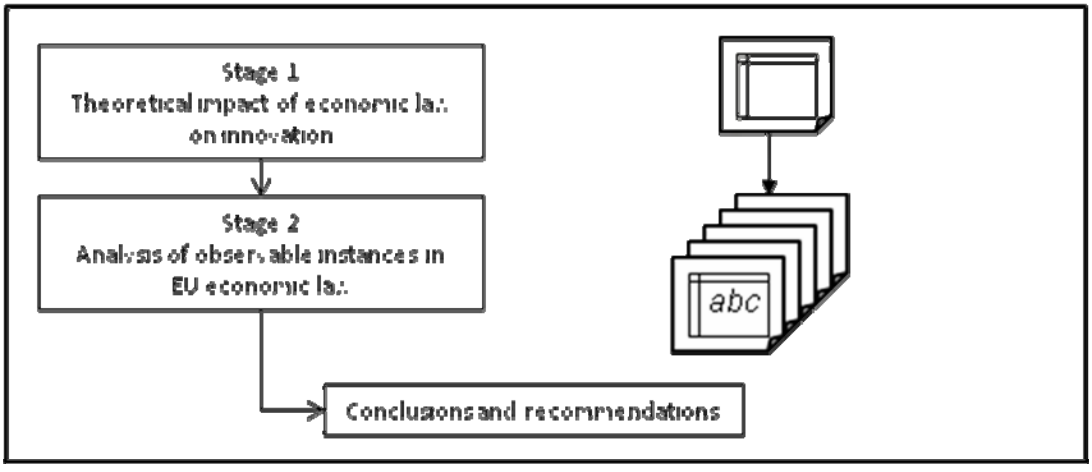
Stage 1 produces an analytical grid for Stage 2.

Stage 2 (analytical): Building on Stage 1, which choices – explicit or implicit – were made regarding innovation in EU economic law? Are the choices coherent across the various observable instances or is there no discernible pattern?

Stage 2 produces a dataset of observable events which are analyzed using the Stage 1 grid.

Conclusions: In the light of Stages 1 and 2, what further research issues arise and what recommendations can be made for reform in the relevant areas?

The project can be represented schematically as follows:



1.2. **Background**

[8] P. Larouche, *Europe and Investment in Infrastructure, with Emphasis on Electronic Communications, in* NEW PERSPECTIVES ON INVESTMENT IN INFRASTRUCTURES 241–269 (W. Dicke and L. Hancher, eds. 2008).

[9] P. Larouche, *The European Microsoft Case at the Crossroads of Competition Policy and Innovation*, 75 ANTITRUST L.J. 933–964 (2009).

Recently, economics progressed significantly in understanding dynamic efficiency and innovation, although many open issues remain. Following the work of Aghion, [10] the place of innovation in economic growth is clearer (building on Schumpeter[11] and Arrow;[12] see also Boone[13] and Boone/van Dijk[14]). Original models of innovation focused too narrowly on the remuneration of the innovator. They were seen as too limitative, even by Chicago scholars such as Landes/Posner.[15] New literature added, among others, the uncertainty inherent in innovation[16] and spillovers from innovation.[17] Business literature distinguished different types of innovation.[18] This led many authors to argue that the traditional analysis might be too favourable to intellectual property protection.[19]

Newer US literature takes a more integrative view, where innovation is the starting point.[20] As a consequence, competition law and intellectual property law are viewed as parts of a larger body of economic law that aims to foster innovation.[21]

In the EU, while much literature explores the interplay between the various areas of economic law – in particular competition law and intellectual property – it remains descriptive and tends to focus on the perceived conflict between these areas: see among others the classical analysis of Govaere[22] or Ullrich,[23] or more recent works such as Anderman,[24] Anderman and

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[10] P. Aghion et al., *Competition and Innovation: An Inverted U Relationship*, 120 Q. J. ECON. 701–728 (2005); P. Aghion and P. Howitt, THE ECONOMICS OF GROWTH (2009).#

[11] J. Schumpeter, CAPITALISM, SOCIALISM AND DEMOCRACY (1947).#

[12] K.J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITIES: ECONOMIC AND SOCIAL FACTORS (R. Nelson, ed. 1962).#

[13] J. Boone, *Competitive Pressure: The Effects on Investment in Product and Process Innovation*, 31 RAND J. ECON. 549–569 (2000).#

[14] J. Boone and T. van Dijk, *Competition and Innovation*, 146 DE ECONOMIST 445–461 (1998).#

[15] W.M. Landes and R. Posner, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW (2003).#

[16] S. Scotchmer, INNOVATION AND INCENTIVES (2004).#

[17] B.H. Frischmann and M.A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257–301 (2007).#

[18] C.M. Christensen, THE INNOVATOR'S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FALL (1997); C.M. Christensen and M.E. Raynor, THE INNOVATOR'S SOLUTION: CREATING AND SUSTAINING SUCCESSFUL GROWTH (2003).#

[19] See M. Boldrin and D.K. Levine, AGAINST INTELLECTUAL MONOPOLY (2008); H. First, *Controlling the Intellectual Property Grab: Protect Innovation, Not Innovators*, 38 RUTGERS L.J. 365–398 (2007); H. Hovenkamp, *United States Antitrust Policy in an Age of IP Expansion*, *in* INTERNATIONAL ANTITRUST LAW AND POLICY: FORDHAM CORPORATE LAW 2004 225–241 (B. Hawk, ed. 2004).#

[20] *See* I. Segal and M. Whinston, *Antitrust in Innovative Industries*, 97 AM. ECON. REV. 1703–1730 (2007); H. Hovenkamp, *Restraints on Innovation*, 29 CARDOZO L. REV. 247–260 (2007); J.M. Barnett, *Property as Process: How Innovation Markets Select Innovation Regimes*, 119 YALE L.J. 384–456 (2009); J.D. Wright, *Antitrust, Multi-Dimensional Competition and Innovation: Do We Have an Antitrust-relevant Theory of Competition Now?*, *in* REGULATING INNOVATION: COMPETITION POLICY AND PATENT LAW UNDER UNCERTAINTY (G.A. Manne and J.D. Wright, eds. 2010).#

[21] J. Farrell and P.J. Weiser, *Modularity, Vertical Integration and Open Access Policies: Towards A Convergence Of Antitrust And Regulation In The Internet Age*, 17 HARVARD J. L. & TECH. 85 (2003); J.B. Baker, *Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation*, 74 ANTITRUST L.J. 575 (2007); C.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34 IOWA J. CORP. L. 1259 (2009); officially endorsed in US Dept of Justice and Federal Trade Commission, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007).#

[22] I. Govaere, THE USE AND ABUSE OF INTELLECTUAL PROPERTY RIGHTS IN EC LAW (1996).#

Schmidt,[25] Drexl,[26] Forrester,[27] Korah,[28] Maher.[29] Some authors[30] and Commission officials[31] adopt a more integrative approach, but they have not fully developed their analysis.

1.3. The components of the project

1.3.1. *Stage 1 – Designing for innovation*

The aim of Stage 1 is to produce a theoretical framework (an analytical grid) for Stage 2 and the conclusions. The main challenge is to bridge the gap between the economic literature on innovation and legal theory and practice. As set out above, while US literature is starting to take an integrative view, in Europe much work remains to be done.

It goes far beyond this project to answer the questions that economists are still grappling with; rather, Stage 1 takes stock of the economic literature (including open questions), organizes it, complements it with legal insights and systematizes it in a way which is useful for legal academic research. For instance, given that economic literature indicates that innovation unfolds differently from one sector to the other, is it possible to design the law so that the approach towards innovation varies according to the sector in question? Similarly, the literature on the choice between proprietary and standardized strategies assumes a simple market (innovator/producer and customer). What if there are intermediary layers which are not innovators but which are affected by the choices of innovators (e.g. the mobile operators)?

Stage 1 results in an analytical grid of the main issues and trade-offs involved in designing law and regulation to foster innovation.

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[23] H. Ullrich, *The Interaction Between Competition Law and Intellectual Property Law – An Overview*, *in* EUROPEAN COMPETITION LAW ANNUAL 2005 – THE INTERACTION BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW (C.D. Ehlermann and I. Anastasiu, eds. 2007).#

[24] S. Anderman, EC COMPETITION LAW AND INTELLECTUAL PROPERTY RIGHTS: THE REGULATION OF INNOVATION (2000); S. Anderman, *The Competition Law/IP 'Interface': An Introductory Note*, *in* THE INTERFACE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND COMPETITION POLICY (S. Anderman, ed. 2007); S. Anderman, THE INTERFACE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND COMPETITION POLICY (S. Anderman, ed. 2007).#

[25] S. Anderman and H. Schmidt, *EC Competition Policy and IPRs*, in THE INTERFACE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND COMPETITION POLICY 37–124 (S. Anderman, ed. 2007).#

[26] J. Drexl, *Is there a 'more economic approach' to intellectual property and competition law?*, *in* RESEARCH HANDBOOK ON COMPETITION AND INTELLECTUAL PROPERTY LAW 27–53 (J. Drexl, ed. 2008).#

[27] I. Forrester, *Regulating Intellectual Property Via Competition? Or Regulating Competition Via Intellectual Property? Competition and Intellectual Property: Ten Years On, the Debate Still Flourishes*, in *EUROPEAN COMPETITION LAW ANNUAL 2005 – THE INTERACTION BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW* 59–90 (C.D. Ehlermann and I. Anastasiu, eds. 2007).#

[28] V. Korah, INTELLECTUAL PROPERTY RIGHTS AND THE EC COMPETITION RULES (2006).#

[29] I. Maher, *The Interface of EC Competition Law and Intellectual Property Rights: the Essential and the Creative*, 7 CAMBRIDGE YB. EUR. LEG. ST. 189 (2004–2005).#

[30] G. Ghidini, INTELLECTUAL PROPERTY AND COMPETITION LAW: THE INNOVATION NEXUS (2006); M.A. Carrier, INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW (2009).#

[31] P. Lowe and L. Peeperkorn, *Intellectual Property: How Special is its Competition Case?*, *in* EUROPEAN COMPETITION LAW ANNUAL 2005 – THE INTERACTION BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW 91–103 (C.D. Ehlermann and I. Anastasiu, eds. 2007); L. Peeperkorn and E. Paulis, *Competition and Innovation: Two Horses Pulling the Same Cart!*, *in* ON THE MERITS: CURRENT ISSUES IN COMPETITION LAW AND POLICY – LIBER AMICORUM PETER PLOMPEN 17–29 (L. Hancher and P. Lugard, eds. 2005).#

1.3.2. *Stage 2 – Analysis of observable instances in EU economic law*

In Stage 2, the grid from Stage 1 is used to analyse observable events from the various areas of economic law so as to ascertain the choices – explicit or implicit – made by decision-makers concerning innovation. Observable events include EU legislation, soft-law instruments (guidelines, statements) as well as decisions of the Commission and of the European courts in individual cases (for competition law in particular). The outcome is a dataset of observable events.

The results from each area are then put together and tested for consistency. In all likelihood, there will not be a consistent approach from one area to the other, and perhaps even within areas. It is quite possible, for instance, that general policy statements and decision practice would diverge.

1.3.3. *Conclusions – Optimal choices for the EU*

The results of Stages 1 and 2 feed into the conclusions, where the inquiry becomes more normative: how could and should economic law evolve towards a coherent approach to innovation, which fits with the rest of EU policy (if it has not done so already)? There is no prior: conceivably, the best choice could also be not to pursue any top-down approach to fostering innovation. A key issue in Stage 3 is whether there is any room and any reason for a specific European approach to innovation. For instance, in contrast to the rather 'individualistic' innovation policy in the USA, Europe seems at first sight to emphasize a more 'collective' approach to innovation, via collaboration among the industry and standardization, etc. The end-result will be a set of recommendations on whether and how EU law should change in the relevant areas in order to follow a consistent and adequate approach to innovation.

1.4. **Methodology**

The overall methodology comes from the experience of the applicant in comparative law methodology over the years, starting with the work accomplished on the *Casebook on Tort Law*.[32] If a comparison between legal systems is executed using a specific fact-pattern or other exogenous function as a starting point, then the outcome (convergence or divergence) will be valid, i.e. it will constitute a valid statement on the two legal systems, as opposed to a statement which could reflect confusion in how the systems are compared. Here this functionalist methodology is applied to solve the apparent tension between the relevant areas: if they share the aim of fostering innovation, when they are analyzed against the background of a solid analytical grid regarding innovation (Stage 1), then any apparent divergence between these areas of law will either disappear or it will be attributed to diverging choices, which can then be reconciled.

2. **AN ILLUSTRATION: RECENT COMPETITION LAW DECISIONS IN THE PHARMACEUTICAL SECTOR**

[32] W. van Gerven, J. Lever and P. Larouche, TORT LAW (2000) (in the series *Ius Commune Casebooks for the Common Law of Europe).*

The pharmaceutical industry is a useful place to begin a study of the role of competition law in innovation for a number of reasons. Patricia Danzon has highlighted two particular characteristics of pharmaceutical markets which make them interesting from a law and economics standpoint. First, standard market analysis of pharmaceuticals "must take into account its unusually high rate of R&D, which implies a high rate of technical change, critical importance of patent protection, potential for market power and novel price and product competitive strategies."[33] Second, the industry is heavily regulated.[34] Furthermore though, unlike other industries that have been at the center of much of the innovation debate up to this point, certain factors that can greatly complicate the analysis are not present in pharmaceuticals. For example, there are not the same network effects as is the case with computer software. Not only may this clarify and simplify the analysis, but it also may provide a useful example to compare to Microsoft to assess the flexibility of the enforcement agencies in adapting their innovation policy to the particulars of the industry. Perhaps the most important reason, however, is that in recent years the rate of radical innovation, in the form of novel drug introduction, has been in decline in both Europe and the US.[35] Because this trend has garnered significant attention from enforcement agencies, we are presented with a situation where the agencies are explicitly attempting to use competition law levers to promote innovation.

Although these factors make pharmaceuticals a very interesting case study for questions related to innovation and the law, they also make that case a difficult one. In recognition of this, the sector has garnered increasing levels of attention in recent years. Major competition law decisions began appearing in 2001, where the conduct targeted ranged from dual pricing schemes[36] and refusals to supply,[37] to allegations of abuse of dominance.[38] Eventually this growing focus on pharmaceuticals led to a sector inquiry, which was completed in July 2009.[39] Each of these efforts demonstrates the Commission's commitment to developing a clearer understanding of the industry, and therefore also of the nature of the innovation that drives much of the competition in the industry. This part will focus on two of these endeavors to explore the debates that arose from them and to glean from them indications of the perceptions of the Commission and the courts with regards to pharmaceutical innovation.

Firstly, we briefly recount the standard narrative regarding the nature of the pharmaceutical industry and the economics of drug innovation (2.1.). Then we will briefly summarize the

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[33] Danzon, *supra* note 41 at 1055.#

[34] *Id.*#

[35] Pharmaceutical Sector Inquiry Final Report, European Commission, Competition DG at ¶ 80 (8 July 2009) (hereinafter "Sector Inquiry Report") (noting that for the years 2000–2007, the average number of novel molecular entities launched was 27, whereas for the years 1995–1999, the average was 40).#

[36] IV/36.957/F3 *Glaxo Wellcome* (notification), IV/36.997/F3 *Aseprofar and Fedifar* (complaint), IV/37.121/F3 *Spain Pharma* (complaint), IV/37.138/F3 *BAI* (complaint), IV/37.380/F3 *EAEPC* (complaint), 8 May 2001, OJ [2001] L 302/1 (holding that Glaxo Wellcome's dual pricing scheme with distributors violated Art. 81 (now Art. 101)) ("Glaxo Spain case").#

[37] Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) v. Glaxosmithkline (C53/03), [2005] 5 C.M.L.R. 1, [2008] 5 C.M.L.R. 20 ("Syfait I") (involving allegations related to GSK's supply quota system aimed at providing only sufficient supplies to meet the demand of the national market, thereby reducing the supply available for arbitrage); Sot Lelos kai Sia EE v. GlaxoSmithKline AEVE, Case C-468/06 ("Syfait II").#

[38] Case T-321/05, AstraZeneca AB and AstraZeneca plc v. European Commission Celex No. 605A0321(1 July 2010).#

[39] Sector Inquiry Report, *supra* note 35. #

Commission's approach to enforcement in the pharmaceutical sector (2.2.). We will present the AstraZeneca case and the two primary approaches to regulatory gaming, and offer a critique on the basis of their probable impact on innovation (2.3.). We will then introduce the ongoing debate over the proper role for industry-specific characteristics in competition law enforcement, as well as discuss the ways in which the common story regarding the nature pharmaceutical innovation has come into question (2.4.).

2.1. **The Economics of Innovation in the Pharmaceutical Industry**

The nature of innovation in the pharmaceutical industry has been the subject of extensive research. As one economist summarized, "[t]he pharmaceutical industry is a textbook example of a science-based sector characterized by high R&D cost, uncertainty and spillovers, for which patent protection assures appropriability, thus providing incentives for innovation."[40] "To the extent that market power exists, it results largely from legal restrictions and other institutional factors" such as patents and the separation of decision makers from payers.[41] While there are two categories of supplier firms in the market, originators and generics, innovation almost exclusively comes from originator firms. Originator firms are "research-based" and "compete[] through innovation," whereas generic firms "compete through the traditional means of price and quality."[42]

The structure of pharmaceutical R&D is in a process of transition and change. There are four main sources of drug R&D: (1) public research institutions, (2) universities, (3) biotechnology companies, and (4) originator drug firms. In recent years, the trend has been towards a disintegration of R&D. The level of basic research carried out by firms in-house has been declining,[43] and originators increasingly enter the process at the development and testing phases.[44] One possible reason why large originator firms have this advantage in the later stages of drug development is risk. Although the risk associated with any particular development effort is very high,[45] the ability of large pharmaceutical firms to diversify across their portfolio of development projects brings the overall risk faced by originators down to average levels.[46] Another contributing factor is that small research firms and biotechnology firms do not usually

[40] Magazzini et al., *Patent Disclosure and R&D Competition in Pharmaceuticals*, 18 ECON. INNOVATION & NEW TECH. 467, 467 (2009).

[41] Patricia M. Danzon, *The Pharmaceutical Industry*, *in* 5880 THE ENCYCLOPEDIA OF LAW & ECONOMICS 1069 (Boudewijn Bouckaert and Gerrit De Geest eds., 1999).

[42] Jürgen Backhaus, *Competition, Innovation and Regulation in the Pharmaceutical Industry*, 4 MANAGERIAL AND DECISION ECONOMICS 107, 109 (1983).

[43] Robert J.W. Tijssen, *Is the Commercialisation of Scientific Research Affecting the Production of Public Knowledge? Global Trends in the Output of Corporate Research Articles*, 33 RESEARCH POLICY 709–733, 727 (2004) ("The observed trends in the output of corporate research articles published in recent years suggest that…corporate basic research is being downsized…").

[44] William S. Comanor, *The Economics of Research and Development in the Pharmaceutical Industry*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 67 (eds. Frank A. Sloan & Chee-Ruey Hsieh 2007).

[45] A study by the Pharmaceutical Research and Manufacturers of America found that for every 10,000 potential compounds investigated by American drug originator firms, only one ultimately successfully is approved for patient use by the FDA. Uwe Reinhardt, *The Pharmaceutical Sector in Health Care*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 31 (eds. Frank A. Sloan & Chee-Ruey Hsieh 2007).

[46] Danzon, *supra* note 41 at 1066.

have the resources required to carry out the testing trials required for regulatory approval. Current estimates suggest that 25-40% of current sales by large originator firms are from products that originated in the biotech sector.[47]

Pharmaceutical innovation can be either radical or incremental.[48] Radical innovations are generally taken to be a new molecular entity (NME).[49] Incremental innovations, on the other hand, fall into one of two categories: (1) follow-on or me-too drugs, and (2) reformulations. Follow-on drugs have been defined as "a new entrant to a therapeutic class that had already been defined by a separate drug entity that was the first in the class to obtain regulatory approval for marketing."[50] Thus, usually this involves a rival originator introducing a competing substitute product to the drug that was first in class.[51] Furthermore, the characterization of follow-on's as incremental may be misleading since there is evidence to suggest that it is not intended to be incremental, but ends up incremental if that particular research effort doesn't reach the market first.[52] Product reformulations, however, almost always involve an originator altering or improving its own product and introducing it as a new version of the original. It is commonly used as a strategy towards the end of a drug's patent life as a means of confronting generic competition.

In terms of innovation as a policy matter, the focus has predominantly been on radical innovation because the originator market is believed to operate according to a blockbuster drug structure. In this model, originator pharmaceutical firms organize their R&D expenditures and efforts around the search for drugs with the greatest revenue potential (based on potential patient population size and that population's ability to pay). This is borne out in econometric studies, which have observed that the distribution of sales revenue in the industry is highly skewed.[53] In 2000, Grabowski & Vernon found that the top decile (in terms of profitability) of drugs accounted for 56% of overall sales revenue.[54]

This skew can be explained as a result of the fact that the originator industry is characterized by fixed costs that are high relative to variable costs. "A consequence of such a cost structure is that, in the short run, it will be profitable for the firm to sell output at prices that cover the lower incremental costs and yield some margin above those costs, but fall far short of

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[47] Comanor, *supra* note 44 at 54.#

[48] It is worth noting that more detailed categorization schemes have been used. *See* Christian Sternitzke, *Knowledge Sources, Patent Protection, and Commercialization of Pharmaceutical Innovations*, 39 RESEARCH POL'Y 810, 813 (2010) (used a four category scheme to differentiate types of innovations: (1) Incremental Innovation – minor changes in the technology base, low extra benefits to consumers; (2) Market Breakthrough – minor changes in technology, high level of consumer benefits; (3) Technology Breakthroughs – novel technology base, low consumer benefit; (4) Radical Innovation – novel technology base, substantial consumer benefit). #

[49] *Id.* #

[50] Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-On Drug Research and Development: Trends in Entry Rates and the Timing of Development*, 22 Supp. 2 PHARMACOECONOMICS 1-14 (2004).#

[51] The optimal mix of first in class drugs to follow-on drugs has been the subject of extensive, and very interesting debate, but further discussion of it is beyond the scope of this article. #

[52] *Id.*#

[53] Henry Grabowski & John Vernon, *The Determinants of Pharmaceutical Research and Development Expenditures*, 10 J. EVOL. ECON. 201 (2000).#

[54] *Id.*#

total average unit costs."[55] This results in many drugs being marketed "despite very small peak revenues and quasi-profits that are a small fraction of mean R&D costs because if the uncertainties surrounding a compound's prospects are not resolved until clinical development is largely complete, most R&D costs are sunk."[56] While it is universally understood that pharmaceutical R&D entails a high rate of failure,[57] late stage failure is especially troublesome because drug testing trials (which is what happens during these later stages of development) are very expensive.[58]

Recently, however, some have argued that this almost exclusive focus on radical innovation has overlooked and disregarded legitimate and meaningful incremental innovations. The incremental innovation associated with drug reformulations, although to a lesser extent than NMEs, requires the dedication of significant R&D resources. One study estimates that post-approval R&D expenditures constitute approximately 25.8% of total R&D expenditures.[59] Furthermore, there is evidence that these incremental innovations may provide significant benefits to consumers. Berndt, Cockburn, & Grepin (2006), in their study of drug utilization and supplemental indications, found that in two of the three drug classes they studied "utilization in patients with diagnoses outside each drug's initially approved indication accounts for 70-80% of total use."[60] They concluded that these results support the notion that incremental innovation seems to constitute an important metric of overall productivity.[61]

Aside from their value as stand-alone innovation directly providing benefits to consumers, product reformulations may also play a role in radical innovation. One possibility arises from the fact that the pharmaceutical industry is one in which knowledge spillovers between firms and from other research sources (government and universities) play an important role. The heavy reliance on patents aids this system by encouraging new knowledge disclosure in patent applications. Both failures and successes can be valuable spillovers.[62] These spillovers can encourage innovation on two levels: (1) increase the likelihood of success of current research efforts by offering insights from other efforts and facilitating in-licensing of developments from other sources; and (2) incentivizing R&D expenditure by firms to enhance their ability to incorporate these spillovers, known as "absorptive capacity".[63] Absorptive capacity is thought to be essential to pharmaceutical R&D efforts because "[a]lthough a public good, science is not a

[55] Reinhardt, *supra* note 45 at 34–35.
[56] *Id.*
[57] A study by the Pharmaceutical Research and Manufacturers of America found that for every 10,000 potential compounds investigated by American drug originator firms, only one ultimately successfully is approved for patient use by the FDA. Uwe Reinhardt, *The Pharmaceutical Sector in Health Care*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 31 (eds. Frank A. Sloan & Chee-Ruey Hsieh 2007).
[58] Comanor, *supra* note 44 at 59 (stating that the cost of clinical trials and other development costs in Phases 2 and 3 constitute more than half of total research and development costs).
[59] DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 185 (2003).
[60] Berndt et al., *supra* note 88 at 81.
[61] *Id.*
[62] Magazzini et al., *supra* note 40 at 469.
[63] *See e.g.*, Wesley M. Cohen and Daniel A. Levinthal, *Innovation and Learning: The Two Faces of R&D*, 99 ECON. J. 569 (1989); Sternitzke, *supra* note 48.

'free' good. Internal scientific capacities are critical for taking advantage of the public good."[64] One recent study concluded that absorptive capacity is more important for generating radical innovations, than for other types of innovation.[65] Thus, the R&D related with product reformulations may spillover into efforts to develop new novel drugs.

The other avenue by which product reformulations may drive radical innovation is that the expectation of potential opportunity for further innovation to improve a product may provide incentives to engage in novel drug development. In other words, it is possible that anticipation of the possibility of improving a product, such as a drug, is an important source of incentives to develop new branded drugs in the first place.[66] Others, however, criticize this suggestion. They argue that full recognition of incremental innovation weakens incentives to generate radical innovations.[67] Thus, the proper balance of these considerations is struck by providing a limited time of patent protection and then encouraging generic entry. "Although generic competition drives out economic profits on brand-name products post patent expiration, rather than rest on their laurels, such competition forces brand-name pharmaceutical manufacturers to invest in new products and maintain a healthy pipeline of products under development."[68] Although there are no definitive answers as to which of these ideas is more accurate, this debate exposes two very different perspectives on the consumer benefits associated with drug reformulations.

At first blush, generic-branded competition appears to be different than many of the other innovation cases we've seen because generics and branded drugs are substitutes for one another, whereas the other cases predominantly involved complementary goods. But part of what makes this theory of harm so complex though is that the drug substitution laws functionally transform the relationship between generics and branded drugs into one with complementary goods characteristics. "The generic manufacturer needs prescriptions for the branded product to take advantage of automatic substitution by the pharmacist…[t]he generic requires the brand to make automatic substitution sales."[69]

The drug reformulation regulatory gaming cases discussed under 2.3. are the product of this disagreement over the value to consumers from these reformulations, combined with the fact that market power in pharmaceuticals arises largely from legal and institutional factors. Depending on the specific form of the reformulated drug, product line extensions may harm generic competition in two ways: (1) delay entry of generics, and/or (2) impeding generic substitution for branded prescriptions. In the US, for example, the introduction of a product line

[64] Comanor, *supra* note 44 *quoting* Alfonso Gambardella, SCIENCE AND INNOVATION: THE U.S. PHARMACEUTICAL INDUSTRY DURING THE 1980S 103 (Cambridge University Press 1995).

[65] Sternitzke, *supra* note 48 at 816.

[66] Berndt et al., *supra* note 88 at 71 ("The available evidence suggests that the prospect of additional sales beyond the initial indication provides commercial justification for extensive R&D expenditure.").

[67] *See* Beatriz Dominguez, Juan Jose Ganuza, & Gerard Llobet, *R&D in the Pharmaceutical Industry: A World of Small Innovations* (Dept. of Economics and Business, Universitat Pompeu Fabra Economics Working Papers) (2005), *available at* http://econpapers.repec.org/paper/upfupfgen/936.htm (concluding that trend towards small innovations in pharmaceuticals is related to the low sensitivity of demand, causing incentives distortion since "small innovations get a proportionally larger reward because pharmaceutical firms target them to the inelastic part of the doctor's induced demand").

[68] Frank A. Sloan and Chee-Ruey Hseih, *Conclusions and Policy Implications*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 270 (2007).

[69] Richard Gilbert, *Holding Innovation to an Antitrust Standard, 3* COMPETITION POL'Y INT'L *47,* 74 (2007).

extension "can prompt a whole new set of Orange Book filings, ANDA Paragraph IV certifications, and litigation-triggered thirty-month stays" and "even without new patent claims," it "delays generic substitution for the new branded product because the firm must file a second ANDA, which faces the same lengthy FDA review as the first one."[70] Strategies to delay generic entry can be particularly important because of the significant role timing plays in the success of the product switch.[71] Product switches are much more difficult, and therefore less likely to succeed, where "generic versions of the old product have already entered the market before or simultaneously with the follow-on product."[72] One possible cause for this are the differences in the nature of the pricing environment in these situations—if generics enter first, the price will have already dropped and therefore switching to a follow-on would involve a price "penalty" on the consumer.[73]

2.2. **The Commission's Approach to Enforcement in Pharmaceuticals**

The past decade has seen a major shift in the approach taken by the Commission towards enforcement efforts in the pharmaceutical sector. The general trend has been away from predominantly intra-brand concerns and towards an emphasis on inter-brand issues. "Traditionally, the Commission's anti-trust enforcement activity in the pharmaceutical sector has focused on removing private obstacles to parallel trade in pharmaceuticals within the Single Market."[74] These intra-brand cases have been pursued under both Article 101 (concerted conduct), as we saw in the *Glaxo Wellcome*[75] case involving the Spanish market, as well as Article 102 (unilateral conduct) as was the case in *Syfait*, which involved GlaxoSmithKline in the Greek market.[76]

In 2005 however, the *AstraZeneca* case (discussed more fully under 2.3.), signaled a major shift in the enforcement priorities of the Commission with respect to pharmaceuticals. This shift was explicitly driven, at least in part, by innovation concerns. According to then Commissioner Kroes, cases like *AstraZeneca* were aimed at the promotion of inter-brand competition "in innovation for patented medicines between the pharmaceutical producers,…, and to encourage inter-brand competition from generic substitutes after patent expiry" thereby increasing price competition.[77] Indeed, in its Pharmaceutical Sector Inquiry Final Report, the Commission asserted that its initiatives include "creating a business environment that stimulates

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[70] *See* Dogan & Lemley, *supra* note 84 at 687.#

[71] Sector Inquiry Report, *supra* note 35 at ¶1010.#

[72] *Id*. at ¶1024. #

[73] The Sector Report quotes a generic producer's explanation in attributing this phenomenon to the pricing environments present in the different scenarios:

> "If the second generation product appears after patent expiry of the original product….The generic will have caused the market price to fall, and thus to switch to the newer product will likely incur a cost penalty to the physician budget, something he is likely to resist unless the second generation is a compellingly better product." *Id*. at ¶1026. #

[74] Nadia De Souza, *Competition in Pharmaceuticals: the challenges ahead post AstraZeneca*, Competition Policy Newsletter No.1 39-43, 39 (Spring 2007).#

[75] *Glaxo Spain*, *supra* note 36.#

[76] *Syfait I*, *supra* note 37. #

[77] *De Souza* at 41 *quoting* Commissioner Neelie Kroes' reply to Oral Question put by the honourable Member of the European Parliament Mr von Boguslaw Sonik (H-0459/06).#

research, boosts valuable innovation and supports the competitiveness of the industry."[78] Alongside this goal, however, the Commission acknowledged that drug prices and public budgets are also a major concern and "are under significant constraints" so "[c]ompetition, in particular competition provided by generic medicines, is essential…"[79]

Although not expressly framed in this way, it seems implicit in this approach that the Commission views vigorous post-patent lapse competition from generics as also contributing to innovation incentives for originator producers. The rationale behind such a perspective would presumably be that generic competition drives down the rents reaped by originators on existing drugs, which motivates them to seek the monopoly rents possible with the development and introduction of novel drugs.

This more nuanced and focused approach indicates that the Commission is intent on taking a more active approach in using competition law enforcement as a tool to stimulate innovation in pharmaceuticals. That being said, however, many questions remain as to the Commission's perspective on many specific innovation policy questions related to competition law enforcement. This paper hopes to highlight two in particular: (1) how to balance and/or prioritize the importance of incremental vs. radical innovation in a particular industry[80]; and (2) the extent to which industry-specific characteristics should influence competition law rules and their application.[81]

2.3. **Drug Reformulation Regulatory Gaming**

As noted above, a distinctive characteristic of the pharmaceutical industry is that it is subject to extensive regulation. Pharmaceutical regulation generally falls into one of two categories. The first category of regulation is that which is intended to protect public health and safety. These regulations control market entry and seek to ensure that only safe drugs are marketed. The second category of regulations is a more heterogeneous group and consists of regulations that are intended to address market competition concerns—particularly the idiosyncrasies of demand for pharmaceutical drugs. For example, information asymmetries exist between patients and physicians, and between physicians and pharmaceutical firms, as to overall efficacy and the price-quality tradeoff of various drugs.[82] This, combined with problems of agency and moral hazard arising from the fact that those responsible for selecting drugs are not the same entity paying for them, results in price being less responsive to quality.[83] A problematic side-effect of imposing broad and wide-ranging regulation covering things like firm entry, product introduction and withdrawal, and using regulations to promote the use of generic drugs where possible, is that it creates opportunities for players to use those regulations to achieve ends

[78] Sector Inquiry Report, *supra* note 35 at ¶ 5.
[79] *Id*. at ¶11.
[80] *See infra* Section 2.3.
[81] *See infra* Section 2.4.
[82] Henry Grabowski, *Competition Between Generic and Branded Drugs*, *in* PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 164 (eds. Frank A. Sloan & Chee-Ruey Hsieh 2007).
[83] Douglas Lundin, *Moral Hazard in Physician Prescription Behavior*, 19 J. HEALTH ECON. 639, 641 (2000) (finding that "[p]atients having to pay a large sum out-of-pocket are less likely to have the trade-name versions prescribed than patients getting most of their costs reimbursed"); *see also* Danzon, *infra* note 41 at 1069.

unintended by regulators. This type of conduct has come to be known as "regulatory gaming" and has been defined as "private behavior that harnesses pro-competitive or neutral regulations and uses them for exclusionary purposes."[84]

Some commentators have gone so far as to suggest that "[t]he pharmaceutical industry presents a perfect storm for regulatory gaming."[85] Indeed, regulatory gaming in the pharmaceutical context has taken many forms.[86] One form in particular though has been receiving increasing attention in recent years in both the US and Europe—follow-on drugs.[87] These drugs are second-generation versions of successful branded drugs, and for this reason have also been called "product line extenders" by the industry. Follow-on drugs commonly take the form of drug reformulations, different dosing protocols, and new delivery methods, sometimes resulting in new indications in which the drug can be used.[88] Critics argue that this practice generally involves little, if any, true innovation and is primarily aimed at delaying generic entry or otherwise hampering the competitiveness of generic drug firms by closing off important means of distribution, which results in higher drug costs.[89] Others, however, defend follow-on drugs as a legitimate form of incremental innovation because they increase the range of products available to consumers and can often offer significant benefits to some or all patients taking the drug.[90]

A major reason why regulatory gaming has attracted so much attention of late is that some have drawn a link between the aforementioned decline in radical drug innovation rates and an uptick in the number of follow-on drugs.[91] Although innovation is usually viewed as the very essence of pro-competitive activity, there has been a judgment by some that these trends are bad for consumers. These concerns are two-fold. First, some have argued that follow-on drugs do not genuinely reflect true innovation and are merely used to disrupt effective generic competition. Others assert a more fundamental objection—arguing that even if these drugs are in some sense innovative, they do not contribute to consumer welfare enough to make up for the welfare lost as

[84] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687 (2009).
[85] *Id*. at 709.
[86] Some commonly observed examples of regulatory gaming in the pharmaceutical industry include obtaining additional patents on already marketed drugs to trigger extensions of patent protection for the drug, withdrawal of marketing authorization just prior to a generic producer obtaining ANDA approval. Jonathan A. Hareid, *In Search of an Elixir: What Ails the Pharmaceutical Industry in Europe and How to Use the Competition Laws to Cure It*, 10 MINN. J.L. SCI. & TECH. 727, 731–32 (2009).
[87] As is the case with many fierce debates, many names have been given to the practice of introducing a new version of a drug towards the end of patent protection for the original version. Some have referred to this practice as "product hopping". We have elected to adopt, what we believe to be, the most objective and unbiased terminology used by the DG Competition in its Sector Report—"follow-on drugs" and "product switches." Sector Inquiry Report, *supra* note 35 at ¶¶987–88.
[88] Ernst R. Berndt, Iain M. Cockburn, and Karen A. Grepin, *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24 Supp.2 PHARMACOECONOMICS 69, 71 (2006).
[89] *See e.g.*, Sector Inquiry Report, *supra* note 35 at ¶1018 (quoting a European consumer association condemning these practices as "evergreening" and resulting in "higher health care expenditures and/or higher prices for consumers"); Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009 (arguing that the combination of settlements and product hopping results in anticompetitive harm).
[90] *See* Berndt et al., *supra* note 88 at 12.
[91] This is at least partly evidenced by the increasing numbers of supplemental drug approvals sought and granted. *Id*.

a result of foregone cost savings arising from reduced use of generic drugs. The notion that enforcement will ultimately benefit consumers, however, relies on the assumption that competition enforcers and courts are able to accurately distinguish between follow-on drugs that are pro-competitive and those that are merely used merely as a mechanism by which to inhibit generic competition; or alternatively, to discern the extent to which the market functions properly, and where it does not, the direction and extent of the market error. The central importance of innovation to competition in pharmaceuticals, the nature of drug R&D, and the two-tiered competition structure involving originators and generics, however, makes assessment of the overall impact of these products very difficult.

There have been a number of cases recently, on both sides of the Atlantic, based upon allegations that regulatory gaming in the context of the introduction of reformulated pharmaceutical markets constituted unlawful single-firm conduct. In *European Commission v. AstraZeneca*, the most recent case decided on the issue, the General Court partially upheld the Commission's decision finding that AstraZeneca had abused its dominant position by withdrawing market authorizations for its blockbuster drug Losec in a small subset of European markets. This contrasts with the two primary US cases on this issue though, where the theory of harm asserted linked the harm to competition with the removal of the old version of the product from the market, and not solely on some regulatory action ancillary to introduction of a product reformulation, as was the case in *AstraZeneca*.

In an industry as heavily regulated and at the same time reliant upon innovation as pharmaceuticals, the question arises as to what impact, if any, enforcement actions against regulatory conduct, necessarily affects the incentives to invest the associated innovative efforts. Evaluating the impact of these enforcement efforts on innovation requires analyzing the nature and process of pharmaceutical innovation, as well as administrative and institutional concerns regarding the practical ability of agencies and courts to formulate rules that accurately distinguish between pro- and anti-competitive regulatory gaming and to consistently apply those rules. Up until now, this form of pharmaceutical regulatory gaming has largely been discussed as a homogeneous category of conduct.[92] In this heading, we suggest that there are important differences amongst the cases alleging anticompetitive conduct involving follow-on drugs—differences which alter the error-cost mix associated with enforcement and, in turn, incentives for innovation.

2.3.1. ***AstraZeneca v. Commission***

In a highly anticipated decision, in July 2010 the General Court of the European Union upheld a decision by the European Commission finding that AstraZeneca (AZ) had abused its dominant position in the market for its popular proton pump inhibitor (PPI), Losec, by withdrawing marketing authorizations in three member states.[93]

[92] *See e.g.*, Jessie Chang, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008); Dogan & Lemley, *supra* note 84.

[93] AstraZeneca, *supra* note 38. The Commission decision had found two separate abuses by AstraZeneca. In addition to the abuse arising from the deregistration of market authorizations, the second abuse found by the Commission was that AZ engaged in a pattern of misleading representations before patent offices in a number of member states.

In extremely brief summary, the facts giving rise to this claim of abuse are as follows. In anticipation of the expiration of patent protection for the active ingredient in Losec, omeprazole, AZ developed a multi-prong strategy to address the impending impact of generic competition. As part of that strategy, AZ developed a new version known as esomeprazole that would serve as the basis for a new patent protected product—Losec MUPS. Once Losec MUPS was completed and ready to be introduced to the market, AZ requested withdrawal of the market authorization for the original capsule form of Losec in Denmark, Norway, and Sweden in 1998.[94] In May 1999, two generics producers filed a complaint alleging that AZ's conduct, namely removal of the market authorizations, prevented them from introducing generic versions of Losec in the European Economic Area markets.[95]

The substance of the claim of abuse alleged that AZ manipulated pharmaceutical regulatory schemes through steps taken in the course of introducing a new tablet version of Losec, to replace the original capsule form. The regulation at issue in the case was Directive 65/65, which provided for an abbreviated procedure for granting marketing authorizations for generic drug products.[96] At the time, in order for a generic company to use the abridged procedure, two requirements had to be satisfied: (1) the reference drug had been authorized in the Community for 6-10 years, and (2) the reference product must still have a valid market authorization in place at the time the generic manufacturer files an application for the abridged procedure.[97] The Commission framed the abuse as follows: the request for deregistration of the marketing authorizations, in combination with AZ's withdrawal of the original form of Losec from the market and the launch of a reformulated version, Losec MUPS, blocked or delayed entry by generic producers and parallel importers, thereby harming competition.[98]

In reviewing the Commission's decision, the General Court was careful to point out, however, that "although [the Commission] defined the abuse of a dominate position as the combination of those elements, the central feature of the abuse consists in the deregistration of the Losec capsule marketing authorizations," the other elements of the abuse merely constituting the context in which the de-registrations were executed.[99] Thus, introduction of the new product form and removal of the old form, alone, would not have constituted an abuse. It was the de-registrations that exceeded the scope of competition on the merits, since this is the "sole element which could be capable of producing the anticompetitive effects alleged by the Commission," namely erecting barriers to entry blocking generics and parallel importers.[100]

AZ made several arguments in its challenge of the Commission's decision. First, AZ asserted that as the holder of the market authorization, it was legal for AZ to "withdraw it as it pleases, or to let it expire, without being obliged to provide a reason in this respect and without concerning itself with the effect of that decision."[101] Second, AZ argued that even dominant

[94] *Id*. at ¶691.
[95] *Id*. at ¶3.
[96] Council Directive 65/65/EEC of 26 January 1965 (Official Journal 022, 09/02/1965, p.0369/0373).
[97] AstraZeneca, *supra* note 38, at ¶617 and ¶666 (discussing Court of Justice decision in previous litigation that held that the directive required this circumstance).
[98] *Id*. at ¶804.
[99] *Id*. at ¶807.
[100] *Id*. at ¶811.
[101] *Id*. at ¶622.

firms are under no obligation to assist competitors and potential competitors by maintaining the market authorization for a drug product the firm is no longer interested in offering, particularly where such maintenance involves ongoing pharmacovigilence obligations.[102] Third, AZ emphasized that generics were not entirely blocked from entering the market because of the availability of the published literature exemption as an alternative means of qualifying for the abridged procedure.[103] Fourth, AZ argued that Losec MUPS was an objectively improved product over the capsule form of Losec, and therefore its introduction was pro-competitive and not exclusionary.[104] Indeed, AZ acknowledged that the purpose of introducing Losec MUPS was to minimize the downward pressure on the price of Losec that would result from the entry of generic versions of omeprazole, but insisted that this does not constitute an abuse.[105]

In upholding the Commission's theory of harm on this charge of abuse, the General Court rejected each of AZ's arguments in turn. According to the General Court, it was irrelevant that under Directive 65/65 it was legal for AZ to request withdrawal of the authorization because "compliance or non-compliance with other legal rules" did not determine the scope of application of Article 82.[106] The court also rejected AZ's proffered objective justification based on the pharmacovigilence requirements. The court noted that AZ was still required to comply with the requirements in the six other member states where AZ continued to offer the capsule form.[107] Moreover, because AZ had held the authorizations for five years, the risk of serious adverse reactions was low.[108] Further undermining this argument was the fact that AZ had not withdrawn its market authorizations in either Germany or the Netherlands, where the company had ceased the sale of Losec capsules, and yet AZ made no argument that the pharmacovigilence requirements were in some way applied in a more burdensome way in the countries where withdrawal was requested.[109] With regards to AZ's argument that the availability of the published literature exemption meant that generics were not entirely blocked from the market and therefore the conduct could not be exclusionary, the court found this argument to fall short. "[T]he fact that the regulatory framework offers an alternative route to obtaining a marketing authorisation does not remove the abusive nature of the conduct of an undertaking in a dominant position where that conduct, considered objectively, has the sole object of making the abridged procedure…unavailable."[110] Finally, the court dismissed AZ's emphasis on the fact that Losec MUPS was a better product than Losec or that the capsules were withdrawn because of consumer preferences, the court found this argument to miss the mark since the Commission was not asserting that the transition of sales from capsules to Losec MUPS itself created any barriers to entry, and therefore did not harm competition themselves.[111]

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[102] *Id*. at ¶635. #
[103] *Id*. at ¶637.#
[104] *Id*. at ¶700 and ¶715. AZ contended that Losec MUPS was better because omeprazole, the active ingredient in Losec, "degrades rapidly and loses its efficacy if it is exposed to the acid conditions of the stomach." *Id*. at ¶715.#
[105] *Id*. at ¶739.#
[106] *Id*. at ¶677.#
[107] *Id*. at ¶658.#
[108] *Id*. at ¶691.#
[109] *Id*. at ¶659, 694.#
[110] *Id*. at ¶829.#
[111] *Id*. at ¶811.#

In summary, according to the General Court, it is not an abuse for a firm to deploy a strategy "whose object…is to minimize erosion of its sales and to enable it to deal with competition from generic products" so long as the strategy does not involve conduct that goes beyond competition on the merits.[112] However, the court went on to state that "an undertaking in a dominant position cannot use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market" absent some objective justification or otherwise related to the defense of some other legitimate consideration of a firm competing on the merits.[113]

2.3.2. *Impact on Innovation Incentives*

The theory of harm advanced in *AstraZeneca* is a subtle divergence from earlier U.S. cases addressing similar conduct,[114] with potentially significant implications for pharmaceutical innovation. One common thread through all of these cases is that they do not allege that the introduction of a reformulated product itself inflicts the harm to competition. Instead, they assert that the harm results from the combining of the introduction of the new version of the drug with conduct to some degree ancillary to that introduction. The General Court in *AstraZeneca* dedicated the most effort to making this distinction clear when it stated numerous times that it was neither the introduction of the new formulation nor the removal of the old formulation, that was the conduct at issue, but instead the combination of those two actions, coupled with the request for withdrawal of market registration.[115] In the U.S. cases, the theory was that combining the introduction of a reformulated product with the withdrawal of the branded (not generic) original version could result in consumer coercion by interfering with drug substitution regulations. Therefore, in the U.S. cases, the courts draw the line at whether or not the "old" version of the drug was removed from the market when the new version was introduced.[116] In *AstraZeneca*, however, the ancillary conduct at issue is an action by the firm within the regulatory scheme that has implications for regulatory recognition of the original version.

The connections between the approach taken in *AstraZeneca* and innovation policy issues are two-fold. First, the fact that the case was pursued as the first abuse of dominance case in pharmaceuticals, when viewed in combination with the Commission's publicly expressed concerns over reduced rates of novel drug introduction,[117] suggests that the Commission views the two phenomena as being related. The arguments made by the Commission in the case support this reading—that this type of regulatory gaming is particularly troubling when it is used as a means of avoiding competition in innovation with other originators. For example, in

[112] *Id*. at ¶804.
[113] *Id*. at ¶817.
[114] *Abbott Laboratories v. Teva Pharmaceuticals*, 432 F.Supp.2d 408 (D.Del.2006) (holding that charges by Teva, a generic pharmaceutical producer, alleging regulatory manipulation were sufficient to support a monopolization claim against Abbott for conduct related to its drug TriCor); *Walgreen Company v. AstraZeneca Pharmaceuticals*, 534 F.Supp.2d 146 (D.D.C. 2008) (dismissing a monopolization claim by Walgreens that AstraZeneca "deliberately switched the market" from its drug Prilosec to a reformulated version called Nexium, on the grounds that AstraZeneca did not remove the Prilosec from the market when it introduced Nexium and therefore there was no consumer coercion).
[115] *AstraZeneca*, *supra* note 38 at ¶646.
[116] *Walgreens*, *supra* note 114 at 151.
[117] Sector Inquiry Report, *supra* note 35 at ¶14 ("In particular, the inquiry sought to examine the reasons for…the apparent decline in innovation as measured by the number of new medicines coming to the market.").

responding to AZ's contention that generic competition was "parasitic", the Commission asserted that "[t]he threat of the entry of generic products forces companies to innovate…"[118] The second way in which this case has implications for innovation policy is that, despite the fact that one of the primary motivations for bringing the case was to ensure sufficient pressure on originators to engage in novel drug innovation, the way that the theory of harm was framed minimizes the negative impact on incentives for legitimate, pro-competitive incremental innovation. It is much simpler to evaluate the effect on competition resulting from a specifically regulatory action that impacts generics directly because there is no need to make a definitive conclusion as to precisely what extent the market is functioning as it should. This is largely attributable to the fact that the approach of the General Court, as compared to the U.S. approach, relies upon more readily accessible evidence and avoids the very difficult process of attempting to measure the value of a particular innovation, and therefore is less likely to result in a false positive.

According to the U.S. cases, where the original version of the product is removed, the conduct is assessed according to the rule of reason test articulated in *Microsoft*.[119] The *Microsoft* court set forth a three-step test: the plaintiff must demonstrate an anticompetitive effect, at which point the burden shifts to the defendant to proffer a pro-competitive justification for the conduct.[120] If the plaintiff offers such a justification, the burden shifts back to the plaintiff to either rebut the justification or establish that "the anticompetitive harm for the conduct outweighs the pro-competitive benefit."[121] Therefore, the court continued, if an anticompetitive harm is established, "that harm will be weighed against any benefits presented by Defendants."[122]

By contrast, in the *AstraZeneca* framework courts and enforcement agencies are not faced with the task of deciphering whether the complexities of the pharmaceutical market leave sufficient room for meaningful consumer choice. In that sense, this approach might be thought of as "pure" regulatory gaming since it really focuses in on specifically regulatory conduct. Narrowing the scope of inquiry and isolating the regulatory action in this way simplifies the inquiry, which makes it less likely to lead to reduced incentives for legitimate innovation than the product substitution theory. There are two primary virtues to the approach in AstraZeneca from the standpoint of error costs. First, the anticompetitive harm alleged is both more severe and its boundaries better defined than that which was asserted in the U.S. cases. In *AstraZeneca*, withdrawal of the market authorizations prevented, or at least significantly delayed, generic entry and parallel imports, thereby eliminating the possibility for consumer choice in favor of generics. In the U.S. cases, on the other hand, where market entry by generics was not prevented (only entry as a direct generic substitute to the reformulated product), commentators have criticized the decision as making the "true gravamen of… [the] allegations…not that consumer choice…was restricted but that an overt choice was required."[123]

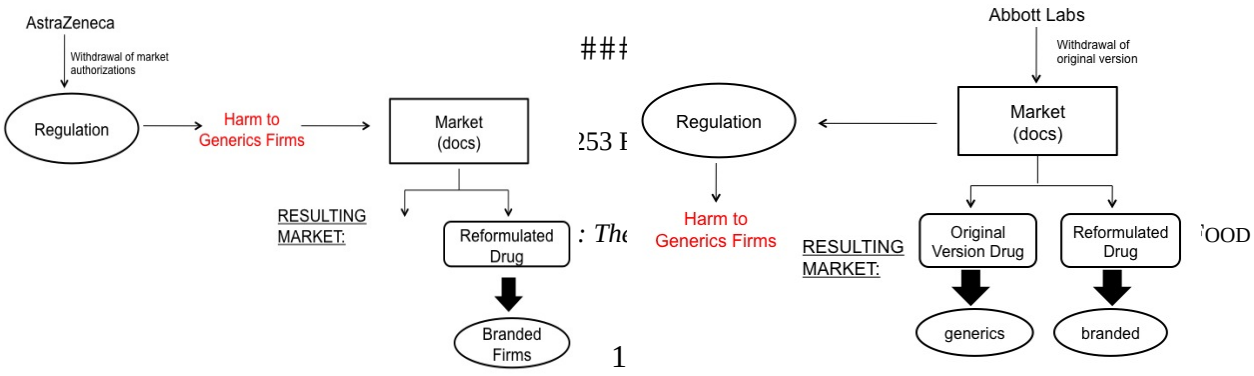

Figure 4.1: "Pure" Regulatory Gaming Theory (EC)

Figure 4.2: Product Substitution Theory of Gaming (US)

The second primary advantage of this approach is that the evidence required to assess whether or not the regulatory action by the firm was justified is more readily available and susceptible to consistent, accurate, and objective evaluation. This arises from the fact that the conduct being assessed is an interaction directly with a regulatory agency, and not an action that is generally considered to be a "business judgment". The value of this approach is demonstrated by the way in which the court assessed AZ's (ultimately unsuccessful) argument that that the pharmacovigilence requirements[124] associated with maintaining market authorizations were onerous and an objective driver of their decision to withdraw the authorizations in the countries they did. To assess the efficacy of this claim, the Commission and the General Court were able to look at AZ's own conduct—particularly whether AZ's conduct with respect to the regulation was consistent across the markets in which it marketed the drugs at issue. Furthermore, the regulatory agency in charge of oversight for the regulation that was allegedly gamed will have a special competence in gauging the burdens of a particular regulation because of its accumulated experience, both across firms and over time.

To illustrate the significance of the attributes of the *AstraZeneca* approach highlighted above, it is useful to compare them to the approach taken in similar U.S. cases. A primary problem with the approach of balancing the value of the specific innovation is that in many product switch scenarios, there will be some basis upon which to argue that the reformulated product is superior to the prior version of the drug,[125] and therefore many product hopping cases will not be screened out by the second step, as was the case for many of the product designs at issue in *Microsoft.*[126] As mentioned previously, these reformulated products often involve improved delivery methods and dosing protocols, and often the use of drugs for new indications. There is research to support the conclusion that these reformulations "can…generate substantial

[124] Pharmacovigilence requirements generally impose ongoing reporting and updating requirements on drug manufacturers for any health or safety issues related to the drug that might become apparent over the drug's product life. *See AstraZeneca*, *supra* note 38 at ¶690.

[125] It is worth noting, however, that there is some ongoing debate as to what should be considered an "objective improvement" in the context of pharmaceuticals. In *Walgreens* the plaintiffs argued that the reformulated version was in no way pharmacologically better in treating the relevant condition. Thus, the fact that drug quality is a multidimensional issue, and may also inform the analysis.

[126] In Microsoft, Microsoft did not offer justifications for many of the product designs at issue in that case and therefore the DC Circuit did not have to proceed to the third step of the analysis.

health benefits."[127] These benefits may take the form of "improved patient compliance, greater efficacy as a result of pharmacokinetics, reduced adverse effects or the ability to effectively treat new patient populations.[128] Likewise, there may also be good reasons for withdrawing an older version of a product from the market when introducing a new one. "It reduces consumer confusion and support costs and focuses retailers on the objective of promoting the new product, all of which can generate consumer benefits."[129] Finally, because of the procedural posture of the U.S. cases, we also have no clear picture of what this third step in the analysis would look like in the case of a legitimate product improvement.[130]

Furthermore, this type of balancing test is problematic because attempts to administer a balancing test to determine the legality of a product withdrawal are prone to erring on the side of finding a violation and therefore condemning what may be a pro-competitive innovation. There are obstacles to accurate measurement on both sides of the scale, as well as to precisely comparing the two sides. These cases require the balancing of the harm to generic competition, which is purely price competition, against the consumer benefit from the reformulated drug product—which is generally non-price competition. The likely or actual impact on drug prices is readily measurable, whereas the benefit from the innovative contribution of the reformulated drug are only partially observable or predictable at the time of product introduction and are almost impossible to quantify in the same manner. On the one hand, it may be possible to measure, or at least estimate, increased utilization of a reformulated drug, which is associated with health and economic benefits.[131] Thus, one metric by which the net benefit of a reformulation can be measured is by the increase in consumer welfare when the drug reaches a broader patient population, facilitates increased compliance with dosing regimens, or otherwise improves a consumer's experience in taking the drug. These can be thought of as direct contributions to welfare. But this is not the only metric we must examine when assessing the benefits of these reformulations.

As mentioned under 2.1. above, the pharmaceutical industry is characterized by a significant level of knowledge spillovers.[132] This means that the R&D from these reformulations may also benefit consumers indirectly by contributing to the effort to develop or improve other drugs. The impact of these spillovers is much more difficult to measure or estimate because they tend to be a long-run benefit. This raises the possibility that they will be discounted in a competition analysis where the benefits are almost entirely realized in the short-term.[133] Therefore objectively and accurately distinguishing between a pro-competitive withdrawal, which is meant to support the introduction of a new, innovative version of the drug, and an "anti-competitive" withdrawal meant only to impede generic substitution, is far more difficult. Because these problems tend to artificially tip the scales in favor of finding a violation, incentives for innovation are potentially negatively impacted.

[127] Berndt et al., *supra* note 88 at 71.
[128] *Id*.
[129] Gilbert, *supra* note 69 at 71.
[130] Dogan & Lemley, *supra* note 84 at 716 (noting that the *Abbott Labs* opinion leaves open the issue of "how a fact finder should go about balancing the precompetitive and anticompetitive effects of a change in formula").
[131] Berndt et al., *supra* note 88 at 73.
[132] *See e.g.*, Magazzini et al., *supra* note 40; Sternitzke, *supra* note 48.
[133] Gilbert, *supra* note 69 at 72 ("In practice, a rule of reason analysis typically focuses attention on short-run benefits and tends to ignore the long-run benefit from innovative activity.")

Even if we were to disregard the impact of spillover effects, the introduction of a reformulation with only marginal benefits over a prior version cannot be assumed to be indicative of anticompetitive intent. Though certainly less risky an endeavor than developing a novel drug[134], it is not always possible to ex ante predict the benefits that will accrue to consumers from an effort to improve a drug. Nonetheless, it will still be rational for an originator to introduce the drug so long as profits exceed marginal cost (which is nominal for drug production), because most of the costs are sunk by the time a drug proceeds through testing.[135]

Some have argued that balancing tests in general are inappropriate for antitrust analyses of innovation. In a recent article, Geoffrey Manne and Joshua Wright argued that antitrust enforcement actions in the context of innovation generally "create[] a special opportunity for antitrust error."[136] Their rationale is that false positives are more costly than false negatives because in the former, "successfully challenging…product innovations is likely to dampen innovation across the economy, whereas Type 2 errors are at least mitigated in part by entry and other competition."[137] Others have argued that the stakes associated with error in an innovation case are "much higher" because "most innovation is beneficial".[138] Richard Gilbert, in his analysis of the various potential tests a court could use to identify so-called "predatory innovation", concluded that "all of [the] tests are likely to produce false positives that chill incentives for beneficial investments in research and development."[139] Manne & Wright have even suggested that there is a bias against innovative products and practices because "courts and economists' initial understanding of these practices" is usually limited, which skews attitudes in favor of enforcement.[140]

2.3.3. *What does this say about innovation policy?*

Ultimately, despite the limited European case law on this form of regulatory gaming, *AstraZeneca* does offer some insights into the contours of the innovation-related thinking in the pharmaceutical sector. There seems to be an implicit presumption that radical innovation is significantly more important to overall competitiveness in the industry than is incremental innovation. By the same token, generic competition is viewed as being an essential source of pressure to drive originators back to competition in innovation post-patent lapse. Thus, while *AstraZeneca* constitutes a measured approach by refraining from broadly condemning product reformulations, the case suggests that actions which interfere with the standard model of upfront patent protection for novel medicines followed by vigorous competition by generics post-patent lapse to drive prices down, will be viewed with a healthy dose of skepticism.

2.4. The *Syfait* Cases: The Debate Regarding Incentives for Innovation, Industry-Specific Characteristics & Competition Law Analysis

[134] Comanor, *supra* note 44 at 64.
[135] *See supra* notes 55–56 and accompanying text.
[136] Geoffrey A. Manne & Joshua D. Wright, *Innovation and the Limits of Antitrust*, J. COMPETITION L. & ECON. 153, 164 (2010).
[137] *Id*. at 167.
[138] Gilbert, *supra* note 69, at 49.
[139] *Id*. at 47.
[140] Manne & Wright, *supra* note 136 at 166.

A pair of relatively recent opinions, arising out of a conflict between GlaxoSmithKline and distributors in Greece who also engaged in parallel trading, brought the debate over two issues central to pharmaceutical innovation and competition law to the forefront.[141] The first is really a question that goes directly to the heart of the debate over pharmaceutical innovation policy—what is the relationship, if any, between parallel trading, firm revenues, and incentives to invest in research and development? The second issue over which these opinions clashed is a much broader question for competition law as a whole: what role should industry-specific characteristics have on the applicability of competition law rules? These opinions express vastly different perspectives on both questions, and this serves both to elucidate some of the points that an innovation policy must address, as well as to demonstrate that vast disagreement on many of those points is possible, and perhaps even likely.

2.4.1. *Industry-Specific Characteristics*

Up to this point, this paper has emphasized many unique characteristics of the pharmaceutical industry and the process of drug innovation. It is important to note, however, that the question of what role industry-specific characteristics should play in competition law analysis remains a matter of intense debate. The controversy is two-pronged. First, should unique industry contexts impact what conduct is considered abusive and/or should such characteristics constitute a legitimate source of for justification for certain types of allegedly abusive conduct? If this first question is answered in the affirmative, the second question is what is the burden faced by the parties for establishing that such characteristics exist and the nature of their effect on competition in the market? This issue has significant implications for innovation policy implementation through competition law because it defines the boundaries as to the extent to which competition rules can be tailored to suit the particularities of a given industry.

The *Syfait* cases involved attempts by GlaxoSmithKline to stem the tide of parallel trading in its pharmaceutical products out of Greece. In 2000, GSK stopped meeting the orders of Greek wholesalers who engaged in parallel trading of the drug products to other Member States, instead supplying hospitals and pharmacies directly. In 2001, GSK recommenced distribution to wholesalers, but limited the supplies distributed to wholesalers to just above national market demand. Wholesalers claimed that these actions constituted an unjustifiable refusal to deal and therefore constituted an abuse of dominant position under Art.82 EC (now Art.102 TFEU). In the case, the Greek competition authority (the EA) identified a number of factors based on unique aspects of the pharmaceutical industry that it believed might impact whether or not the conduct at issue was objectively justified and made inquiry with the CFI as to whether they could play a role in justifying the conduct. The Commission argued that refusals to supply by a dominant firm could only be justified in a narrow set of circumstances and that none of the factors identified by the Greek competition authority were relevant considerations for justifying a refusal to deal.

While both the CFI and ECJ opinions acknowledge that in certain circumstances the features of a market rise to the level of creating a distinctive context that should be taken into account in assessing whether certain conduct can be justified, the opinions diverged considerably

[141] *Syfait I*, *supra* note 76; *Syfait II*, *supra* note 37.

in their assessment of whether the pharmaceutical sector constitutes such an altered environment. In the CFI opinion, Advocate General Jacobs held that a refusal to supply "is capable of objective justification, and thus of not constituting an abuse, where the price differential giving rise to the parallel trade is the result of State intervention in the Member State of export…, given the combined circumstances of the European pharmaceutical sector at the current stage of its development…"[142] AG Jacobs went on to identify four factors in particular that make the pharmaceutical sector unique and are therefore relevant to determining whether a refusal to supply is justified: (1) the "pervasive and diverse State intervention in the pricing of pharmaceuticals"; (2) the regulation by the Community and the Member States of the distribution of pharmaceutical products establishing nationally demarcated obligations upon pharmaceutical firms; (3) the "potentially negative consequences of parallel trade for competition…and incentives to innovate"; (4) the fact that the end consumers of pharmaceutical products cannot be assumed to benefit from parallel trade.[143] What this holding clearly indicates is a willingness on the part of AG Jacobs to tailor a competition law analysis in a way that is "highly specific to the pharmaceutical industry in its current condition."[144]

In *Syfait II*, however, AG Colomer took a very different view of the nature of the pharmaceutical industry in holding that GSK could not justify its policies against parallel trade. According to AG Colomer, the control and regulation of drug product prices by Member States "does not entirely remove the prices of those products from the law of supply and demand"[145] and therefore Art.82 cannot be applied differently in the pharmaceutical sector on that basis.[146] Although AG Colomer ultimately rejected all of the justifications proffered by GSK, he ultimately left the door open for justification analysis to take some account of the unique nature of price regulation in pharmaceuticals. Though he did not offer much in the way of specific guidance on how the analysis would work, he did note that "it cannot be ignored that…State intervention is one of the factors liable to create opportunities for parallel trade."[147]

2.4.2. ***Relationship between parallel trading and innovation incentives***

Among the factors he found to be particularly relevant to the analysis of whether GSK's conduct was justified, AG Jacobs found it "relevant to consider some of the economic factors affecting the commercial policy of pharmaceutical undertakings."[148] Because production in pharmaceuticals is characterized by high fixed costs and relatively low variable costs, by the time a drug reaches the market, most of the costs are sunk and it is therefore rational for a drug company to bring a drug to market so long as the price is above variable cost. Therefore, "[t]he mere fact that a product is marketed on a given market at a given price does not mean that a pharmaceuticals undertaking could recoup its total costs if that price were generalized across the whole of the Community."[149]

[142] *Syfait I*, *supra* note 37 at ¶ 105.
[143] *Id*.
[144] *Id*. at 101.
[145] *Syfait II*, *supra* note 37 at 1424.
[146] *Id*. at 1422.
[147] *Id*. at 1425–26.
[148] *Id*. at ¶89.
[149] *Id*.

According to AG Jacobs, this cost structure, together with the fact that pharmaceutical price and distribution are regulated in a nationally segregated manner, and that parallel trading, by definition, undermines national price differentials, suggests that parallel trading threatens to undermine incentives for pharmaceutical firms to invest in research and development.[150] In other words, the fact that drug prices are regulated along national market lines allows firms to market drugs even in markets where the low prices established would not otherwise cover total costs, but parallel trading destabilizes this system by undermining the firm's ability to make up in high price markets what is not covered by sales in low price markets. If a firm is unable to cover its total costs, it is unlikely to invest in developing the drugs in the first place. Therefore, according to AG Jacobs, a pharmaceutical firm may be justified in making certain efforts to stem parallel trading.

AG Colomer, however, entirely dismissed the argument that parallel trading may negatively affect incentives for research & development, stating that "no causal link between the repercussions of parallel trade on the revenues of pharmaceutical companies and those companies' investments in research and development" had been established.[151]

Thus, while there seems to be some agreement on the principle that industry-specific characteristics may have a role to play in competition law analysis in certain circumstances, the fact that these two opinions articulate almost entirely contradictory perspectives on the pharmaceutical industry highlights one of the major obstacles to effectively incorporating industry-specific insights into legal rules and analysis. Economics does not always offer clear answers to what drives innovation.

Furthermore, at least in the pharmaceutical sector, the structure and process of R&D along with our understanding of it, is evolving in ways that may undermine the applicability of the standard narrative regarding what drives drug innovation that was laid out under 2.1. above. Indeed, in recent years there has been a trend towards disintegration in pharmaceutical R&D.[152] An increasing number of innovations are originating outside of the major pharmaceutical firms, instead coming from smaller firms (especially biopharmaceutical outfits), with "the major drug companies only entering the process at the development and testing phases."[153] Another poignant example of this is the argument made by Boldrin & Levine in their book *Against Intellectual Monopoly*, questioning the almost universal assumption[154] that pharmaceutical innovation, more than innovation in almost any other industry, depends heavily upon strong patent protection.[155] Thus, the fact that many of these issues remain in flux and a matter of sharp debate complicate their incorporation into a coherent, consistent approach to competition law analysis.

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[150] *Id*. at ¶93.#

[151] *Id*.#

[152] *See supra* notes 20-24 and accompanying text.#

[153] Comanor, *supra* note 44 at 67. *See also* Tijssen, R.J.W., *Is the Commercialization of Scientific Research Affecting the Production of Public Knowledge?: Global trends in the Output of Corporate Research Articles*, 33 RESEARCH POLICY 709 (2004) (finding that the level of basic research coming from the industry has been declining recently).#

[154] *See* Sector Inquiry Report, *supra* note 35 at ¶9 ("Intellectual property rights are a key element in the promotion of innovation" and are "particularly important for the pharmaceutical sector…").#

[155] *See* Boldrin & Levine, *supra* note 19 at 212–38.#

3. CONCLUSION

The study of recent competition law developments in the pharmaceutical sector is intended as an illustration of the research approach set out in Part 1 of this article. Although this study is in no way exhaustive, it does provide some insights as to how the Commission and European courts are approaching innovation in this industry. First, the *Syfait* cases suggest that while industry-specific characteristics may have a role to play in narrow circumstances, the burden of justifying conduct on the basis of protecting incentives to invest in innovation will be high. Furthermore, there is vast disagreement over what drives investments in pharmaceutical R&D and the extent to which state intervention alters the competitive environment in the market. The limited context of regulatory gaming also contributes tour understanding of now prevailing pharmaceutical innovation policy in competition law. The arguments of the Commission along with the General Court's opinion in *AstraZeneca* suggests a skepticism regarding the impact of incremental innovation in the form of reformulated drugs on consumer welfare. The very fact that the case was brought may reflect a judgment by the Commission that radical innovation is far more important to competition in the pharmaceutical sector and a concern that incremental innovation, as a less risky and less expensive endeavor, will draw resources away from novel drug development. It is important to note, however, that given that the Final Pharmaceutical Sector Report was released only just over a year ago, the prospect of increasing levels of enforcement in this industry, together with the continuing evolution of the structure of pharmaceutical R&D, means that we should expect continued development of these perspectives in coming years.